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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,017	12/21/2001	William S. Dalton	114205.1501	4208

7590 06/17/2003

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EXAMINER	
TELLER, ROY R	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,017	DALTON ET AL.	
	Examin r	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This office action is in response to Paper No: 14, received 1/ 7/03. Claims 1-19 will be examined.

Claim Objections

Claims 3, 8, and 13 are objected to because of the following informalities: 37 CFR 1.821(d) requires the use of the assigned sequence identifier (SEQ ID NO:) in all instances where the description of a patent application refers to a sequence and whenever a sequence or fragment thereof is claimed (see MPEP 2422.03). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the

enablement requirement for the following reasons:

The nature of the invention: The invention is drawn to a method of inhibiting cell adhesion mediated drug resistance in a patient, comprising administering to the patient an effective amount of a peptide. The peptide comprises at least one D- amino acid or a variant thereof. The peptide comprises RZ-3. The method enhances the efficacy of chemotherapy or radiation therapy in a patient. The method is for treating cancer in a patient, where the cancer is a myeloma or multiple myeloma.

The state of the prior art and the predictability or lack thereof in the art: Claim 1 recites a method for inhibiting cell adhesion mediated drug resistance in a patient, comprising administering to the patient an effective amount of a peptide. The instant specification recites " it is also known that certain resistance mechanisms may only be functional *in vivo*..." , see page 2, lines 20-21. Dermer, Biotechnology, 1994, vol. 12, page 320, teaches that cell lines in which cancer is usually studied are unsuitable for the job. They do not mimic conditions in the human body, see second paragraph. Finally, based on the teaching of unpredictability regarding *in vivo* therapy which are taught in the prior art, persons skilled in the art would not associate *in vitro* results (all the working examples in the instant specification are *in vitro* results) with *in vivo* therapeutic efficacy. Applicant's specification fails to contain sufficient disclosure to overcome the teachings of unpredictability which are found in the art. *Ex parte Balzarini* 21 USPQ2d 1892 (Bd Pat Appl & Int. 1991).

Claim 6 recites a method for enhancing the efficacy of chemotherapy or radiation therapy in a patient, comprising administering an effective amount of the peptide. The instant

specification recites " it is also known that certain resistance mechanisms may only be functional *in vivo*..." , see page 2, lines 20-21. Dermer, Biotechnology, 1994, vol. 12, page 320, teaches that cell lines in which cancer is usually studied are unsuitable for the job. They do not mimic conditions in the human body, see second paragraph. Finally, based on the teaching of unpredictability regarding *in vivo* therapy which are taught in the prior art, persons skilled in the art would not associate *in vitro* results (all the working examples in the instant specification are *in vitro* results) with *in vivo* therapeutic efficacy. Applicant's specification fails to contain sufficient disclosure to overcome the teachings of unpredictability which are found in the art. *Ex parte Balzarini* 21 USPQ2d 1892 (Bd Pat Appl & Int. 1991).

Claim 11 recites a method for treating cancer in a patient, comprising administering to the patient an effective amount of the peptide. The instant specification recites " it is also known that certain resistance mechanisms may only be functional *in vivo*..." , see page 2, lines 20-21. Dermer, Biotechnology, 1994, vol. 12, page 320, teaches that cell lines in which cancer is usually studied are unsuitable for the job. They do not mimic conditions in the human body, see second paragraph. Finally, based on the teaching of unpredictability regarding *in vivo* therapy which are taught in the prior art, persons skilled in the art would not associate *in vitro* results (all the working examples in the instant specification are *in vitro* results) with *in vivo* therapeutic efficacy. Applicant's specification fails to contain sufficient disclosure to overcome the teachings of unpredictability which are found in the art. *Ex parte Balzarini* 21 USPQ2d 1892 (Bd Pat Appl & Int. 1991).

The amount of direction or guidance present and the presence or absence of working

examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). Direction or guidance is not found in the specification to enable the use of the peptide *in vivo* in patients. The D-amino acid is not enabled for *in vivo* use in patients. The peptide comprising at least one D-amino acid is not enabled for *in vivo* use in patients. A variant of the peptide is not enabled for *in vivo* use in patients. See reasons outlined *supra*.

The breadth of the claims and the quantity of experimentation needed: The claims recite a method of treatment comprising administering a peptide to a patient in need thereof. The instant specification does not enable the *in vivo* use of the peptide, as only *in vitro* working examples are shown in the instant specification. The quantity of experimentation needed to enable the invention is burdensome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 8, 9, 13, 14, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 8, 13, and 18 recite "...or a variant thereof." This is indefinite as to the metes and bounds of the variant. The instant specification lists a variety of variants on page 14, lines 8-16, but the claims recite **a** variant.

Claims 4, 9, and 14 recite "...peptide comprises RZ-3." This is indefinite. It is unclear if applicant is claiming a peptide comprising the sequence of RZ-3 or is claiming a composition comprising RZ-3.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT
1654
6/13/03

RT

Brenda Brumback
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SUPERVISORY PATENT EXAMINER
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